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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

NEKTAR THERAPEUTICS,

Plaintiff,

vs.

ELI LILLY & CO.,

Defendant.

CASE NO. 3:23-cv-03943

JOINT PRETRIAL STATEMENT

Hon. James Donato
Trial Date: October 27, 2025
Location: Courtroom 11

Pursuant to the Court's Standing Order for Civil Jury Trials, Plaintiff Nektar Therapeutics ("Nektar") and Defendant Eli Lilly and Company ("Lilly"), hereby submit their Joint Pretrial Statement.

I. Substance of the Action

Nektar asserts causes of action against Lilly for breach of contract and breach of the implied covenant of good faith and fair dealing relating to a License Agreement between Nektar and Lilly ("License Agreement") for the development of Nektar's drug, Rezpeg. Lilly denies Nektar's claims and denies that Nektar may recover any damages.

a. Nektar's Statement

This dispute arises from Lilly's failure to fulfill its promises made in a written contract to use "Commercially Reasonable Efforts" ("CRE") to develop and commercialize Nektar's promising new drug, Rezpeg, and Lilly's bad faith attempts to delay and thwart Rezpeg's entry into the market.

Before the parties entered into the written contract, Nektar invented and was developing Rezpeg to treat autoimmune diseases. Rezpeg has a new mechanism of action that works by stimulating regulatory cells ("T-Regs"), which restore balance to patients' immune systems. In addition to its potential to treat several well-known autoimmune diseases and skin conditions such as systemic lupus erythematosus ("lupus") and atopic dermatitis (or eczema) that affect upwards of 5% of the population, Rezpeg offers unique benefits over existing therapies. For example, early studies suggest Rezpeg's benefits continue for extended periods even after treatment ends, unlike many drugs that require continued use.

Several companies were interested in collaborating on Rezpeg's development, but Nektar chose to contract with Lilly given Lilly's expertise in developing autoimmune drugs and its purported desire to commit its considerable resources to develop Rezpeg. To ensure Lilly's commitment to Rezpeg, Nektar bargained for specific, stringent protections that were incorporated into the written contract, including an obligation that Lilly use commercially reasonable efforts to develop and commercialize Rezpeg. This required Lilly—the world's largest pharmaceutical company and maker of some of the most widely sold injectable drugs (like Rezpeg)—to develop and commercialize Rezpeg using the efforts, expertise, and resources Lilly normally uses to develop and commercialize

its own comparable drugs.

At trial, Nektar will prove that Lilly repeatedly breached its obligation to use commercial reasonable efforts and the implied covenant of good faith and fair dealing. Lilly breached the contract in multiple ways, including the following: First, Lilly subjected Rezpeg to different standards than its comparable drugs being developed to treat the same diseases as Rezpeg. This includes incorporating interim analysis and "futility" plans into Rezpeg's clinical trials that are unlike any trial plans Lilly had ever endorsed for another drug, and that were specifically designed to enable a "quick kill" of Rezpeg. ECF No. 228-2, Ex. 12.

Second, Lilly assigned untrained and inexperienced employees to Rezpeg's development efforts who botched and published critical calculations that dramatically and inaccurately understated how effective Rezpeg was in treating eczema and psoriasis (which did not happen for comparable drugs). Lilly could have prevented these errors by paying even a modicum of attention to Rezpeg or treating Rezpeg like its other drugs, for which Lilly ran independent programming checks on all primary and key secondary [endpoints]." ECF No. 228-3, Ex. 49. Lilly did not run those programs for Rezpeg. *Id.*, Exs 44, 45

Third, Lilly delayed Rezpeg's development (and no other drug) to favor Lilly's internal candidates and abandoned already approved and funded development of Rezpeg (but no other drug). Despite Rezpeg establishing "proof of concept" in its Phase 1 eczema trial in September 2021—the gating criteria Lilly placed on Rezpeg moving to Phase 2—and Lilly agreeing to initiate a Phase 2 eczema trial for Rezpeg in Q1 2022, Lilly still had not initiated (and was nowhere close to initiating) that trial by April 2023, when Lilly informed Nektar that it was terminating the parties' contract.

Fourth, Lilly abandoned Rezpeg's development as a lupus and eczema treatment even though Rezpeg showed the potential to have market-leading efficacy against both diseases and vastly improve patients' lives. Lilly cannot identify any lupus or eczema drug that it terminated with comparable efficacy results. In fact, the only eczema and lupus drugs Lilly terminated before Phase 3 were, unlike Rezpeg, less efficacious than the placebo.

Lilly's treatment of Rezpeg starkly contrasts with Lilly's efforts to develop its own eczema and lupus treatments, including Lilly devoting years of work and spending hundreds of millions on

trials for drugs with no better potential to effectively treat patients than Rezpeg and worse track records of safety issues.

Lilly's argument that it followed its normal practices in developing Rezpeg cannot be squared with the record. Nektar will prove that Lilly's own employees and expert consultants disagreed with Lilly's approach, admitting it did not make "scientific sense," and opposed Lilly's delays to Rezpeg's development. ECF No. 228-2, Ex. 16.

Further, documents uncovered by Nektar have revealed that after paying more than $1 billion to acquire a competitor to Rezpeg several years after contracting with Nektar to develop Rezpeg, Lilly pivoted and schemed to delay or put an end to Rezpeg's development entirely. As internal Lilly communications reveal, rather than exercising its right to terminate the License Agreement, Lilly executed a strategy to put Rezpeg on "life support" and "take it off later" to "avoid a law suit" with Nektar. *Id.*, Exs. 15, 16. Lilly did this by inventing excuses to delay Rezpeg development while its other drugs advanced, all while "hid[ing] the timelines" to ensure Nektar "ha[d] no clue." *Id.*, Exs. 15, 18, 25. Lilly's principal excuse—that delaying Rezpeg was necessary so Lilly could find a way to address non-medically serious injection site reactions that purportedly reduced Rezpeg's potential for commercial success—is disproven by Lilly own documents projecting billions of dollars in Rezpeg sales and Lilly's pursuit of eczema and lupus drugs with far more serious, indeed fatal side effects, like cancer. But despite Rezpeg's promising commercial success, and its obligation to development Rezpeg, Lilly favored its own drugs, knowing that it would keep all the profits from those sales, as opposed to having to share the profits from Rezpeg's sales with Nektar.

Nektar will also prove that Lilly breached its obligation under the License Agreement to follow Good Research Practices in developing Rezpeg. Among other things, Lilly failed to perform standard data checks and reviews when performing calculations to determine the effectiveness of Rezpeg in treating patients, failed to assign qualified personnel to perform such checks and calculations, and failed to provide accurate reporting of such information, resulting in dramatically and inaccurately understating how effective Rezpeg was in treating certain diseases. Lilly also broke its promise to return critical Rezpeg materials to Nektar after terminating the License Agreement despite an express obligation to do so.

Nektar will further prove that Lilly's breaches damaged Nektar by delaying Rezpeg's development for years and diminishing Rezpeg's value. Nektar had an expectation in receiving future milestones and royalties for Rezpeg. By delaying and abandoning Rezpeg's eczema and lupus development, Lilly's significantly harmed that interest before terminating the License Agreement in April 2023, leaving Nektar with a drug that was years behind in development and tarnished with a false and inaccurate record of being only moderately effective in treating patients. Lilly offers no contrary evidence on damages (nor could it); it merely raises baseless legal arguments and offers expert testimony by a statistician with no drug development expertise who simply illustrates the impact that certain adjustments (which he is unqualified to endorse) could have on Nektar's damages model.

b. **Lilly's Statement**

Unhappy with the fact that its once-promising treatment candidate Rezpeg failed to reach the market, Nektar brought this lawsuit against Lilly seeking a windfall payment on top of the more than [redacted] dollars in value it has already received from Lilly under the License Agreement. Each of Nektar's claims fail. At trial, Lilly will prove that it complied with the Commercially Reasonable Efforts clause in its License Agreement: it invested hundreds of millions of dollars over six years into Rezpeg, painstakingly seeking to overcome the challenges to developing Rezpeg for lupus and atopic dermatitis. Despite the stories Nektar spins about a scheme to thwart Rezpeg, Nektar fails to identify a single instance in which Lilly deviated from its normal practices. Rather, the real reason for Rezpeg's failure is as clear as it is common in the industry—poor clinical trial results that showed it could not compete with existing treatments and baseball sized injection site reactions that made it unattractive to potential patients.

In 2017, Lilly and Nektar entered the License Agreement to develop Rezpeg. Lilly paid Nektar a lump sum of $150 million, and committed to spending millions more, for the right to license and develop Rezpeg as Nektar's partner. The pharmaceutical development process is risky, and Lilly negotiated contractual protections to account for that uncertainty.

To start, Lilly's obligation to develop Rezpeg was governed by the CRE clause. The CRE clause did not guarantee Rezpeg's success; nor did it specify which steps Lilly had to take while

developing Rezpeg. Instead, the CRE clause required Lilly to expend "effort, expertise and resources normally used by [Lilly] in the development and/or commercialization of a comparable pharmaceutical product Controlled by [Lilly] which is … at a similar stage of development," and "will be determined on an Indication-by-Indication and country-by-country basis." ECF No. 32-2 at 3-4. The contract also allowed Lilly to consider "relevant strategic and commercial factors normally considered" by Lilly, including "issues of safety and efficacy, product profile, [and] the competitiveness of the marketplace." *Id.*

Both parties also recognized that disagreements could arise regarding Rezpeg's development. Consequently, the License Agreement established committees charged with making development decisions over Rezpeg comprised of an equal number of Lilly and Nektar representatives that required unanimity. If the committees were deadlocked, Nektar could invoke a dispute resolution framework that escalated decisions to the companies' respective executives. If the parties remained deadlocked after this process played out, the License Agreement required final resolution [redacted] following completion of the Initial Development Phase early in the parties' collaboration. ECF No. 33-2 § 3.7(b) (emphasis added).

Finally, Lilly secured the right to terminate the partnership at will and return Rezpeg to Nektar. ECF No. 32-2 § 11.2. Although Lilly was hopeful about Rezpeg's potential, the at-will termination protected Lilly if Rezpeg's trial results were unsatisfactory. Yet, if Lilly exercised that right, Lilly would return ownership of Rezpeg to Nektar, which would then have the exclusive right to develop and commercialize Rezpeg on its own and receive 100% of the potential upside of that commercialization, leaving Lilly no chance to recoup its multi-million dollar investment in Rezpeg's development. *Id.* § 11.4. Nektar expressly waived any claim to "lost profits" in any litigation following Lilly's at-will termination. *Id.* § 10.6.

Lilly more than complied with the CRE clause. Over six years, Lilly invested an additional [redacted] (over and above its initial $150 million payment), as well as significant employee time and resources, into Rezpeg's development. Despite these efforts, Rezpeg failed to produce acceptable clinical trial results. A Phase 2 clinical trial for lupus failed to meet the parties' agreed-upon end points. And Rezpeg often caused significant injection-site reactions ("ISRs") in patients—including

baseball-sized irritations and inflammations that persisted for weeks. These ISRs raised both efficacy and tolerability concerns regarding Rezpeg, because patients don't want treatments that cause significant rashes—particularly for atopic dermatitis, when a hugely successful competitor drug already on the market did not produce such dramatic or frequent adverse skin reactions. Following these developments, Nektar asked Lilly to terminate the License Agreement, and Lilly did so.

At trial, Lilly will show that Nektar cannot demonstrate any breach of the License Agreement or recoverable damages. Nektar's theories ignore the plain text of the License Agreement that limited Lilly's obligations, forbade Nektar from second-guessing Lilly's judgments (judgments Nektar agreed with at the time, and never elevated to the dispute resolution framework), and curtailed potential damages.

First, Nektar cannot prove that Lilly breached the License Agreement. The notion that Lilly's years of effort and nine-figure investment somehow amounted to a failure to exercise "commercially reasonable efforts" to develop Rezpeg is absurd. At bottom, Nektar complaints are not about Lilly's ***efforts***, but rather about supposedly [redacted] along the way. ECF No. 210-3, Robin Tr. at 138:8-20 (emphasis added). None of those criticisms implicate the commercial reasonableness of Lilly's efforts, much less show that Lilly's efforts fell short of the efforts that Lilly expended on a [redacted] that was [redacted] as Rezpeg. ECF No. 210-2 at 3.

Nor can Nektar now second-guess judgments it agreed with during the collaboration and that it never once invoked the escalation process to resolve. For example, Nektar second-guesses Lilly's [redacted] for a lupus indication after a Phase 2 clinical trial failed to meet the measures by which the parties had agreed the trial would be judged. ECF No. 210-4, Rao Rep. ¶ 75. But Nektar agreed to the critical success factors Lilly applied to that decision; Lilly simply evaluated the results of that trial based on the jointly predetermined success criteria. Nektar also flyspecks Lilly's design of Rezpeg's atopic dermatitis trials by complaining about a "rethink" of trial design that occurred after the parties learned that efforts to mitigate Rezpeg's ISRs had failed. This, too, is no more than a naked attack on Lilly's judgments, specifically about how best to position Rezpeg in a complex market.

Nektar also complains that a subcontractor miscalculated one piece of data regarding Rezpeg's Phase 1 effectiveness in treating atopic dermatitis, and that Lilly did not catch the mistake. But this miscalculation did not impact Rezpeg's development because its reported efficacy score still met the pre-set threshold for continuing development, and Lilly indeed began the process of designing a Phase 2 study in atopic dermatitis. Beyond the fact that this subcontractor error did not impact Rezpeg's development, Nektar again fails to tie its complaint to the CRE provision. Lilly was obliged only to expend commercially reasonable efforts, expertise, and resources, and Lilly nowhere promised that no errors—including materially inconsequential ones like the miscalculation here—would ever occur in numerous trials across a multiyear development process.

Even if Nektar could show a breach (and it cannot), it still could not show that any alleged breach caused it damages. Nektar asserts two theories of harm; neither has merit. First, Nektar claims it has been deprived of future milestone or royalty payments that it might have earned under the License Agreement had Rezpeg progressed further in the development process. But the terms of the License Agreement foreclose this theory. Rezpeg never hit the contractually defined milestones that might have entitled Nektar to additional payments from Lilly. And Lilly's intervening at-will termination before Rezpeg hit those milestones—a termination Nektar expressly ***demanded***—cut off any obligation for Lilly to make future milestone or royalty payments under the License Agreement. To the extent Nektar argues that Lilly's termination resulted in Nektar incurring additional costs to develop Rezpeg on its own, this is equally foreclosed by operation of the License Agreement's termination provision.

Second, Nektar argues that there was a delay in Rezpeg's development, reducing Rezpeg's hypothetical future commercial prospects. But Nektar fails to show any causal connection between the alleged breaches by Lilly and the supposed delay. And on top of that, the License Agreement squarely forecloses this theory of liability, too. As relevant here, the parties agreed that neither would be liable to the other "FOR REMOTE, SPECULATIVE, PUNITIVE OR EXEMPLARY, OR OTHER SPECIAL DAMAGES, ***INCLUDING LOST PROFITS***." ECF No. 32-2 at §10.6 (emphasis added).

At trial, Lilly will also show that Nektar's secondary claims lack merit. Nektar's claim under New York's implied covenant of good faith and fair dealing fails for the same reasons as its breach of contract claim. And Nektar has failed to identify any Rezpeg-related materials that Lilly supposedly failed to return after Lilly terminated the License Agreement.

II. Relief Requested

a. Nektar's Requested Relief

Nektar seeks the following relief:

1. Monetary damages, including Nektar's increased cost of developing Rezpeg on its own, milestone payments under the contract, and diminution in Rezpeg's value;
2. Pre- and post-judgment interest;
3. Costs and expenses in connection with this action, including attorneys' fees; and
4. Injunctive relief ordering Lilly to return all requested materials related to Rezpeg that it has not yet provided to Nektar.

b. Lilly's Requested Relief

Lilly denies that Nektar is entitled to relief of any kind.

III. Undisputed Facts

The Parties agree that the following facts are undisputed and will stipulate for incorporation into the trial record without the necessity of supporting testimony or exhibits.

A. The Parties

1. Nektar is a biopharmaceutical company headquartered in San Francisco, California, and is the owner of Rezpeg.
2. Lilly is a medicine company headquartered in Indianapolis, Indiana.

B. License Agreement

3. Nektar and Lilly entered into the License Agreement on July 23, 2017.
4. The License Agreement was a valid contract.

IV. Disputed Factual Issues

The Parties dispute the following factual issues:

1. Whether Lilly breached its License Agreement with Nektar.

2. Whether Nektar suffered damages caused by any alleged breach by Lilly of the License Agreement and, if so, the amount of Nektar's damages.
3. Whether Lilly breached the implied covenant of good faith and fair dealing with Nektar.
4. Whether Nektar suffered damages caused by any alleged breach by Lilly of the implied covenant of good faith and fair dealing and, if so, the amount of Nektar's damages.
5. Whether Lilly acted with gross negligence or reckless misconduct in its development of Rezpeg.

V. Disputed Legal Issues

The Parties dispute the following legal issues:

1. Whether Schedule 4.8 of the License Agreement (Good Research Practices) imposes obligations on Lilly, or only on Nektar.
2. Whether Nektar is entitled to attorneys' fees, costs, and injunctive relief.
3. Whether Nektar's damages are barred by the License Agreement's limitation of liability provision.
4. Whether Nektar can recover milestone or royalty payments following Lilly's termination of the License Agreement as damages for pre-termination breaches.
5. Whether Nektar's implied covenant of good faith and fair dealing claim is legally viable.
6. Whether Nektar's claimed damages (if any) are recoverable under the License Agreement.

VI. Stipulations

The Parties propose that the following stipulations be entered:

1. That the Undisputed Facts identified in Section III, *supra*, be entered into the trial record.
2. Documents created by a party and thereafter produced by that party in this case and identified in the final agreed exhibit lists that are submitted to the Court are presumed prima facie genuine and authentic pursuant to Federal Rule of Evidence 901. Nothing shall prohibit a party from offering argument or evidence to rebut these presumptions, objecting to the admissibility of a document or communication on any other grounds, or from otherwise seeking admittance of any documents or communications.

3. Exhibits shown to a witness on the stand to which no objection has been made will be received into evidence by operation of the Final Pretrial Order without the need for additional foundational testimony.

4. Each party will identify witnesses to be called live and by deposition testimony, including the reasonably anticipated order of presentation, by email, no later than 7:00 p.m. Pacific Time three business days in advance of the day of trial during which the witnesses will testify. For example, if a witness will testify live on a Tuesday, the presenting party must identify the witness by 7:00 p.m. Pacific Time the prior Thursday. Such notice must indicate the intended order of call and whether the witness will be presented live or by deposition.

5. Lilly proposes: For witnesses who will testify live, if that witness is called by a party other than the party controlling the witness, that party will provide the notice required by Section VI(4) to the party controlling the witness at least 7 days before the start of trial. Nektar proposes that, for witnesses who will testify live, if that witness is called by a party other than the controlling party, that party will provide the notice required by Section VI(4) to the party controlling the witness at least five business days (instead of three) in advance of the day of trial during which the witnesses will testify.

6. Lilly proposes: By September 30, 2025, each party shall identify to the other party any witness outside of the requesting party's control that the requesting party intends to call live at trial in the requesting party's case in chief. By October 2, 2025, the non-requesting party shall notify the requesting party whether the live witness will attend trial live. Nektar proposes that outstanding issues regarding witness availability be resolved at the Pretrial Conference on October 9, 2025, after which the parties can agree to an identification and notice procedure.

7. The parties agree that any party may use the testimony of any witness (whether on direct or cross-examination) presented by any party in their case-in-chief.

8. Witnesses will only be called once at trial even if they appear on both parties' witnesses lists and cross-examination shall not be limited to the scope of direct for those witnesses

on both parties' witness lists to avoid having to call a live witness twice during both parties' cases. For adverse witnesses a party calls in its case-in-chief, that party will cross-examine those witnesses, and then the opposing party will put on a direct examination that is not limited by the cross.

9. All fact witnesses, except for a corporate representative for each party, will be sequestered during trial prior to their testimony. Expert witnesses will not be sequestered.

10. Lilly proposes: For expert witnesses who will testify live, if any party calls an expert within their control to support their case-in-chief (an 'affirmative expert'), the opposing party may, at their option, call an expert within their control to present rebuttal testimony (a 'rebuttal expert') immediately following the conclusion of the affirmative expert's direct and cross examination. Nektar's counsel included this language in its initial proposed pretrial statement and only later proposed removing it. The Court has followed this process before and should do so here because it promotes efficiency and prevents juror confusion. *See, e.g.*, Pretrial Order at 5, *Speck v. CBS Corporation*, No. 20-cv-05845-JD (N.D. Cal. June 25, 2024), ECF No. 512 ("The parties should schedule the presentation of expert testimony to occur back-to-back by subject matter."). Nektar disagrees that Lilly's expert witnesses should be called in Nektar's case-in-chief. Lilly's proposal is unworkable, as certain of Lilly's experts rebut multiple of Nektar's experts.

VII. Bifurcation

The parties' position is that bifurcation or a separate trial of specific issues is not required.

VIII. Settlement

The parties have had settlement discussions with their mediator, Ambassador Jeff Bleich, but have been unable to reach an agreement. Nektar remains willing to engage in settlement discussions. Given that Mr. Bleich recently assumed a full-time position as General Counsel for a bay area company, Nektar proposed that continuing discussions be overseen by either a magistrate

judge or private mediator. Lilly has invited Nektar to propose a new private mediator, which Nektar is considering.

IX. Estimated Trial Length

Trial is currently set to begin on October 27, 2025.

The parties currently estimate that the total length of the trial will be 20 hours per side, not inclusive of jury selection and opening and closing statements.

X. Pending Motions

Lilly's motions to seek sanctions against Nektar's failure to preserve Teams messages, ECF Nos. 142-2 and 185-2, remain pending.

Lilly's motion for summary judgment, filed on May 22, 2025, ECF No. 206, also remains pending.

Lilly's motion to voluntarily dismiss counterclaims with prejudice, filed on September 19, 2025, ECF No. 252, also remains pending.

DATED: September 25, 2025

Respectfully submitted,

QUINN EMANUEL URQUHART & SULLIVAN, LLP

s/ Yury Kapgan
Yury Kapgan

Counsel for Plaintiff Nektar Therapeutics

DATED: September 25, 2025

Respectfully submitted,

KIRKLAND & ELLIS, LLP

s/ Ryan Moorman
Ryan Moorman

Counsel for Defendant Eli Lilly and Company

ATTESTATION PURSUANT TO CIVIL L.R. 5-1(I)(3)

I, John ("Mickey") McCauley, am the ECF user whose user ID and password are being used to file this document. I hereby attest that concurrence in the filing of this document has been obtained from each of the other signatories.

By /s/ *John McCauley*
John McCauley